ROSS ARONSTAM & MORITZ LLP

100 S. West Street, Suite 400 • Wilmington, DE 19801
Telephone 302.576.1600 • Facsimile 302.576.1100
Benjamin J. Schladweiler
bschladweiler@ramllp.com

January 27, 2017

The Honorable Sherry R. Fallon
844 N. King Street, Room 6100, Unit 14
Wilmington, Delaware 19801-3555

Re: *AbbVie Inc., et al. v. Amgen Inc., et al.*, C.A. No. 16-666-SLR-SRF

Dear Judge Fallon:

AbbVie respectfully responds to Amgen's letter of January 26, 2017.

I. Protective Order

A. Citizen's Petition Bar: Amgen's only argument is that bars "on citizen petitions to the FDA … ha[ve] not previously been litigated in this Court." D.I. 38 at 2. This is an odd assertion, given that AbbVie directed Amgen to three cases back in December where this Court denied regulatory bars in the face of arguments relating to citizen-petition activity. For example, in *Cephalon, Inc. v. Impax Labs., Inc.*, No. 11-1152-SLR (D. Del. June 29, 2012), the proponent argued unsuccessfully that citizen petitions should be barred. Ex. 6 (letter brief); D.I. 37, Ex. 1 at 2 (order); *see also* D.I. 37 Ex. 3 at 2 (bar "'from participating in FDA petitioning activity'"); Ex. 7, *Mayne Pharma Int'l Pty Ltd. v. Merck & Co., Inc.*, No. 15-438-LPS, D.I. 47 at 3:25-4:1 (D. Del. Mar. 4, 2016) (bar proponent's "concern" included "citizen[] petition[s] to FDA").

B. Application of Bars to Non-Lawyers: *Edwards Lifesciences AG v. CoreValve, Inc.*, 2011 WL 10565589, at *1 (D. Del. Feb. 23, 2011) is inapposite. *See* Ex. 5, *Edwards* Protective Order, ¶¶ 4, 6. There, the party sought to amend an agreed-upon expert prosecution bar had the burden to show good cause. *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1381 (Fed. Cir. 2010). Here, the burden is reversed: as the party arguing for a broader bar, Amgen bears the burden to show good cause. *Id.* at 1378, 1381. Moreover, the experts AbbVie wishes to use in prosecution—those with no involvement in claim scope, *see* D.I. 37 at 2—will not engage in the "competitive decisionmaking" activities that the Federal Circuit has identified as worth protecting in the prosecution context, namely, activities which provide the "opportunity to control the content of patent applications and the direction and scope of protection sought." *Deutsche Bank*, 605 F.3d at 1380.

C. Duration of Bars: Amgen concedes that the "bars should expire *one year* after … the last litigation." D.I. 38 at 1 (emphasis added). But then contradictorily argues that one year after withdrawal is insufficient because "AbbVie cannot claim that within only a year (or even longer) counsel will completely forget Amgen's confidential information to the point they can fairly engage in previously-restricted activities." *Id.* If one year is sufficient in one context, it must be sufficient in the other—the same memory issues exist. And information learned during litigation would almost certainly be stale one year later for purposes of competitive decision-making and regulatory bars. Amgen's inconsistent argument fails to "show that … the duration of the bar … reasonably reflect[s] the risk presented by the disclosure of proprietary competitive information." *Deutsche Bank*, 605 F.3d at 1381.

II. Amgen's Request to Modify the Court's September 15, 2016 Order (D.I. 18)

On September 15, 2016, the Court ordered that "[a]bsent agreement of the parties, the court's Default Standard for Discovery … shall govern discovery of paper and electronic documents." D.I. 18 at ¶ 3. Amgen now seeks to modify the Court's Order.

A. Custodian Limit: Paragraph 3(a) of the Court-ordered Default Standard limits the number of custodians that must be searched by each party to 10. In light of this order, AbbVie agreed and the Court ordered a substantial completion date of May 5, 2017. On November 10, 2016 AbbVie disclosed its ten custodians. During this time, the parties discussed Amgen's proposal to modify the Default Standard, yet Amgen *never* suggested enlarging the number of AbbVie custodians until January 18, 2017.[1] More than four months after the Court's Order and two months after AbbVie identified its custodians, Amgen now seeks to quintuple the number of custodians, from 10 to more than 50. That request should be denied for three reasons.

First, Amgen's request is months too late, and it would be impossible for AbbVie to comply by the May 5 completion date. Amgen could have made this request at the scheduling conference, as it knew the number of inventors and could have asked for the prosecuting attorneys. If Amgen had, AbbVie would have objected, and never could have agreed to the date. *Second*, Amgen provides no reason why it needs each inventor's e-mail, as AbbVie is producing e-mail from at least one inventor on every patent, non-custodial documents, and relevant lab notebooks for each inventor. It is very rare in patent cases that key validity documents come from e-mail, so Amgen asks to search for a needle in a haystack. Yet the burden would be immense. Based on AbbVie's current custodians, Amgen's requests for all inventors could add well over 20 million *additional* pages for review. *Third*, Amgen has not even named, much less provided specific relevance, for searching patent prosecution counsel (both in-house and outside). There is no inequitable conduct claim or other claim or defense that would make this even potentially relevant. Amgen's untimely request should be denied.

B. Privilege Log Exceptions: Amgen previously proposed that neither party would be required to log privileged communications with outside counsel or their work product. Ex. 8, at 5. AbbVie agrees. One day before demanding a discovery conference[2], however, Amgen insisted on an exception for AbbVie documents relating to prosecution. *Id.* Amgen's new proposal would drastically and unilaterally increase the burden on AbbVie for no good reason, and should be rejected. But if the Court orders AbbVie to do so, Amgen should likewise be required to log documents regarding (i) AbbVie patents and applications and (ii) Amgen's aBLA.

---

[1] Amgen's attempt to excuse its delay by pointing to the parties' negotiation of the *search term* portion of Paragraph 5(b) is misleading. In fact, during these negotiations Amgen confirmed that 3(a) applied. *See* Ex. 8, 1 n.1. And in any event, Amgen has known since November 10, 2016, the 10 custodians AbbVie planned to search and never objected until last week.

[2] Amgen raised many of its "disputes" a day before requesting this conference, and refused to tell AbbVie what it was moving on until less than 48 hours before opening briefs. AbbVie hopes the parties can avoid unnecessarily burdening the Court in the future, by following Local Rule 7.1.1.

III. Requests for Production

Rule 26(b)(1) limits discovery to "nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering … whether the burden or expense of the proposed discovery outweighs its likely benefit." *See also Gilead Scis., Inc. v. Merck & Co.*, 2016 WL 146574, at *1 (N.D. Cal. Jan. 13, 2016) ("No longer is it good enough to hope that the information sought might lead to the discovery of admissible evidence."). Amgen's fishing expeditions are the type of requests the amendment seeks to avoid.

A. RFP 15: Amgen's RFP 15 requests each component used to perform the assay claimed in the '666 patent, including "the reference standard" and "the Z-leucine-arginine-MAC substrate." The '666 patent specifically teaches that the requested substrate can be obtained from R&D Systems. *Id.* at 112:34-35. And the other components listed in the claim NaOAc (sodium acetate), DTT (dithiothreitol), and EDTA are all widely-used and publicly available from a chemical purveyor such as Sigma Aldrich (although it would be surprising if Amgen or its experts did not have them in their laboratories already). As to the "reference standard," this is not recited in any claim of the '666 patent. D.I. 38-1, Ex. G, Claim 1.

B. RFP 25: Amgen asks AbbVie to produce all documents served or received in any Humira litigations. This amounts to ***over 100 proceedings,*** and tens or hundreds of millions of pages, the ***vast majority*** of which have ***nothing to do with this case***. This would include millions of pages of third-parties' confidential information, and involve seeking court orders to modify dozens of protective orders and amending third-party agreements. AbbVie has instead agreed to produce the filings in the three proceedings involving a patent-in-suit or a U.S. family member, which is even more than required by Amgen's *Inventio* case. *Compare* D.I. 38, Amgen Letter at 3 (citing *Inventio* for the proposition that "[d]iscovery concerning litigation involving the same or similar patents and products is permitted, especially when the documents concern claim construction or validity" *with Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 662 F.Supp.2d 375, 382 (D. Del. 2009) ("The mere fact that both the New York Action and the instant litigation involve similar patents is not itself sufficient for a finding of relevancy pursuant to Rule 26."). Instead, the court ordered the production of six deposition transcripts and a group of letters because a specific case for relevancy for each document had been made. *Inventio*, 662 F.Supp.2d at 382-84; *see also Wyeth v. Impax Labs.*, 248 F.R.D. 169, 170-71 (D. Del. 2006). Amgen has made no such showing here.

C. RFPs 9 and 10: Amgen seeks all documents relating to prosecution of the Patents-in-Suit or "Related Patents," but neglects to mention that its definition of "Related Patents" is not limited to family members (as is typical), but rather includes *all* patents relating to adalimumab, including but not limited to more than 50 additional patents that Amgen is accused of infringing, but refused to litigate under the BPCIA. D.I. 38-1, Ex. E at 4; D.I. 1 at ¶¶7-8. Having made that choice, Amgen cannot now get discovery on the patents it excluded. *See* Ex. 9, *Amgen Inc., et al. v. Hospira, Inc.*, C.A. No. 15-839 (RGA) (denying Amgen discovery on patents it could have sued on under the BPCIA but did not). AbbVie is willing to produce prosecution discovery on the patents-in-suit and U.S. family members, but anything more would be excessive. With respect to the scope of the documents, given the vast overbreadth of Amgen's custodian request and its refusal to implement reasonable limitations on privilege logs, it is clear Amgen seeks to send AbbVie on a massive privilege logging exercise. It proffers no explanation of relevance, much less one that would justify such a burden.

D. Default Standard Paragraph 4(e): AbbVie has consistently stated that it will follow Paragraph 4(e) of the Default Standard and has even agreed to go beyond the requirements of 4(e) and waive its protections for documents supporting or refuting evidence of any secondary considerations asserted by AbbVie, and other categories not at issue here.

Documents Concerning Humira and its Manufacture and Alleged Prior Art References: AbbVie has never stated it would rely on 4(e) to shield documents related to asserted prior art references (despite Amgen's refusal to produce *any* discovery on certain art *it* asserted, *e.g.*, Ex. 10, RFP 39). With respect to documents relating to Humira, on the meet and confer, the parties agreed that some (but not all) Humira documents from prior to 2010 would need to be produced. But instead of negotiating what this subset should be, Amgen appears now to be arguing *all* documents relating to Humira should be produced, essentially eviscerating 4(e). Given Humira has been on the market since 2003, has been the subject of around 150 clinical trials, and is worked on by thousands of employees, the burden would be enormous. And only a small percentage of these documents might relate to Amgen's allegations of Humira as prior art. So here again, Amgen hopes for a needle in a haystack. Instead, AbbVie proposes producing documents sufficient to show how Humira has been manufactured from launch to the filing of the complaint.

Patent Prosecution Documents and Underlying Data: AbbVie has agreed to produce certified file histories for all patents-in-suit and U.S. patents in the same families. With respect to other prosecution documents, such documents exist in every case, yet 4(e) does not exclude them as it does other categories. Amgen has not made any showing, much less shown good cause, why such documents should be excluded here. *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc*., 2016 WL 859229, at *2 (D. Del. March 3, 2016) (noting "if the possible existence of some other relevant, non-produced documents was always enough to demonstrate good cause to abandon the Default Standard's requirements, the Standard would be worth little."). Amgen's proposal to effectively rewrite Paragraph 4(e) should be denied.

Documents Concerning the First Public Disclosure, Use, Demonstration, Offer for Sale, Sale and/or Commercial Use: Again, AbbVie will produce documents that show how Humira has been manufactured from launch to the filing of the Complaint. Amgen's unbounded request otherwise is unworkable and inconsistent with Paragraph 4(e) and Fed. R. Civ. P. 26(b)(1).

General Objections: Amgen's request that AbbVie provide a detailed description of the documents it is withholding based on its general objections on an RFP-by-RFP basis is: (i) contrary to Fed. R. Civ. P. 34 (*see* Advisory Committee Note to 2015 Amendment ("The producing party does not need to provide a detailed description or log of all documents withheld, but does need to alert other parties to the fact that documents have been withheld.")); (ii) contrary to the court-ordered Default Standard's Paragraph 1(b) on proportionality (*see* D.I. 38-1 at 2-3 (describing how Amgen's responses to RFPs not only do not provide a description of the documents withheld but also do not provide a description of the documents that will be produced)); (iii) premature with respect to many general objections given AbbVie has not completed document production and therefore does not know what will be withheld (*id.* at 2); and (iv) non-sensical as applied to certain objections (*id.* at 4 (describing issue for general objection 9 relating to inaccurate assumptions by Amgen)). Pursuant to the Federal Rules, AbbVie has stated what it will produce for each RFP which "qualifies as a statement that the materials have been withheld." Amgen's request to depart from those rules should be denied.

Respectfully submitted,

/s/ Benjamin J. Schladweiler

Benjamin J. Schladweiler (#4601)

cc: All Counsel of Record